Rule R444-14. Rule for the Certification of Environmental Laboratories.

As in effect on March 1, 2000

Sections

R444-14-1. Introduction.

(1) This rule is authorized by Utah Code Section 26-1-30(2)(m).

(2) This rule applies to laboratories that analyze samples for compliance with Federal Safe Drinking Water Act, Federal Clean Water Act, and the Federal Resource Conservation and Recovery Act.

(3) A laboratory that analyzes samples for compliance with rules established by the Utah Department of Environmental Quality that require that the analysis be conducted by a certified laboratory, must become certified under this rule and comply with its provisions.

(4) A laboratory that, under subcontract with another laboratory, analyzes samples for compliance with rules established by the Utah Department of Environmental Quality that require that the analysis be conducted by a certified laboratory, must become certified under this rule and comply with its provisions.

(5) A laboratory certified under this rule to analyze samples for compliance with rules established by the Utah Department of Environmental Quality that require that the analysis be conducted by a certified laboratory must also obtain approval under this rule for each method used to analyze each analyte.

R444-14-2. Definitions.

(1) "Accuracy" means the degree of agreement between an observed value and an accepted reference value.

(2) "Analyte" means the substance or thing for which a sample is analyzed to determine its presence or quantity.

(3) "Approved" means the determination by the department that a certified laboratory may analyze for an analyte or interdependent analyte group under this rule.

(4) "Assessment" means the process of inspecting, testing and documenting findings for purposes of certification or to determine compliance with this rule.

(5) "Batch" means a group of analytical samples of the same matrix processed together, including extraction, digestion, concentration and the application of the analytic method, using the same process, personnel, and lot(s) of reagents.

(6) "Certification officer" means a representative of the department who conducts assessments. This representative may be a third party contractor who conducts assessments and acts under the authority of the department.

(7) "Clean Water Act" means U.S. Public Law 92-500, as amended, governing water pollution control programs.

(8) "Contamination" means the effect caused by the introduction of the target analyte from an outside source into the test system.

(9) "Deny" means to totally or partially refuse to certify a laboratory.

(10) "Department" means the Utah Department of Health.

(11) "Equipment blank" means sample that is known not to contain the target analyte and that is used to check the cleanliness of sampling devices, collected in a sample container from a clean sample-collection device and returned to the laboratory as a sample.

(12) "Field blank" means a sample that is known not to contain the target analyte and that is used to check for analytical artifacts or contamination introduced by sampling and analytical procedures, carried to the sampling site, exposed to

sampling conditions and returned to the laboratory and treated as an environmental sample.

(13) "Holding time" means the maximum time that a sample may be held prior to preparation or analysis.

(14) "Interdependent analyte group" means a group of analytes, as determined by the department, for which the ability to correctly identify and quantify a single analyte in the group indicates the ability to correctly identify and quantify other analytes in the group.

(15) "Initial demonstration of analytical capability" means the procedure described in the method 40 CFR Part 136, Appendix A, used to determine a laboratory's accuracy and precision in applying an analytical method.

(16) "Instrument blank" means a sample that is known not to contain the target analyte, processed through the instrumental steps of the measurement process used to determine the absence of instrument contamination for the determinative method.

(17) "Interference" means the effect on the final result caused by the sample matrix.

(18) "Key personnel" means the technical director, and laboratory quality assurance officer, all of whom meet the qualification requirements of this rule.

(19) "Matrix" means a surrounding substance within which something originates, develops, or is contained, such as: drinking water, saline/estuarine water, aqueous substance other than drinking water or saline/estuarine water, non-aqueous liquid, biological tissue, solids, soils, chemical waste, and air.

(20) "Matrix spike" means a sample prepared to determine the effect of the matrix on a method's recovery efficiency by adding a known amount of the target analyte to a specified amount of matrix sample for which an independent estimate of the target analyte concentration is available.

(21) "Method detection limit" means the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than, zero as determined from analysis of a sample containing the analyte in a given matrix as described in 40 CFR Part 136, Appendix B, 1 July 1995 edition.

(22) "Precision" means the degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

(23) "Preservation" means the temperature control or the addition of a substance to maintain the chemical or biological integrity of the target analyte.

(24) "Proficiency testing audit" means the event, including the receiving, analyzing, and reporting of results from a set of samples that a proficiency testing provider sends to a laboratory, for the laboratory to comply with the proficiency testing requirements of this rule.

(25) "Proficiency testing program" means a program that meets the National Environmental Laboratory Accreditation Conference(NELAC) proficiency testing standards and that is provided by a National Environmental Laboratory Accreditation Program(NELAP)-authorized proficiency testing provider or a program that is provided by the EPA as part of its WS and WP audits.

(26) "Revoke" means to withdraw a certified laboratory's certification or the approval for a certified laboratory to perform one or more specified methods.

(27) "Resource Conservation and Recovery Act" means U.S. Public Law 94-580, as amended, governing solid and hazardous waste programs.

(28) "Safe Drinking Water Act" means U.S. Public Law 93-523 94-580, as amended, governing drinking water programs.

(29) "Selectivity" means the capability of a method or instrument to respond to the target analyte in the presence of other substances or things.

(30) "Sensitivity" means the capability of a method or instrument to discriminate between measurement responses representing different levels of a target analyte.

(31) "Standard operating procedures (SOPs)" means a written document which details the steps of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and is accepted as the procedure for performing certain routine or repetitive tasks.

(32) "Surrogate" means a substance which is unlikely to be found in the environment and which has properties that mimic the target analyte and that is added to a sample to check for quality control.

(33) "Suspend" means to temporarily remove a laboratory's certification or the approval for a certified laboratory to perform one or more specified methods for a defined period not to exceed six months.

(34) "Target analyte" means the analyte that a test is designed to detect or quantify.

(35) "Technical employee" means a designated individual who performs the analytical method and associated techniques.

(36) "Trip blank" means a sample known not to contain the target analyte that is carried to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.

R444-14-3. Laboratory Certification.

(1) A laboratory is the organization and facilities established for testing samples.

(2) A laboratory that conducts tests that are required by Department of Environmental Quality rules to be conducted by a certified laboratory must be certified under this rule.

(3) To become certified, to renew certification, or to become recertified under this rule, a laboratory must:

(a) submit a completed application to the Division of Epidemiology and Laboratory Services, Bureau of Laboratory Improvement, on forms provided by the department; the application shall include:

(i) the legal name of the laboratory;

(ii) the name of the laboratory owner;

(iii) the laboratory mailing address;

(iv) the full address of location of the laboratory;

(v) the laboratory hours of operation;

(vi) a description of qualifications of key personnel and technical employees;

(vii) the name and day-time phone number of the laboratory director;

(viii) the name and day-time phone number of the quality assurance officer;

(ix) the name and day-time phone number of the laboratory contact person;

(x) an indication of class of laboratory for which the laboratory is applying for certification under this rule; and

(xi) the laboratory's quality assurance plan and documentation of the laboratory's implementation and adherence to the quality assurance plan.

(b) be enrolled in a proficiency testing program;

(c) apply for approval to analyze at least one analyte or interdependent analyte group by a method the department may approve under this rule; and

(d) pay all fees prior to the department's processing of the application.

(e) submit a statement of assurance of compliance signed and dated by the laboratory owner, director, and quality assurance officer, which shall include:

(i) an acknowledgment that the applicant understands that, once certified, the laboratory must continually comply with this rule and shall be subject to the penalties provided in this rule for failure to maintain compliance;

(ii) an acknowledgment that the department may make unannounced assessments and that a refusal to allow entry by the department's representatives is grounds for denial or revocation of certification;

(iii) a statement that the applicant laboratory will perform all proficiency testing audits according to the accepted method and in accordance with department requirements; and

(iv) a statement that there is no misrepresentation in the information provided in the application.

(4) Upon satisfaction of the requirements of subsection (4):

(a) the department shall conduct an on-site assessment at a date and time agreed to by the laboratory director to determine whether the laboratory complies with the minimum requirements of this rule and that the laboratory can produce valid results;

(b) the department shall provide the laboratory director a written report of the department's findings from the on-site assessment; and

(c) if the department determines that the laboratory does not meet the requirements for certification, the laboratory shall develop and submit a plan of correction acceptable to the department.

(5) The department shall issue a final decision and letter upon a satisfactory on-site assessment or within 30 days of acceptance of the plan or portions of a plan of correction. The letter shall state whether the laboratory is certified or not certified. It shall also state the approval status of the analyte or interdependent analyte group for which the laboratory applied for approval. The department may certify a laboratory for up to one year.

(6) A certification expires at the expiration date listed on the certificate, unless otherwise revoked. To avoid a lapse in certification, a laboratory must submit a completed application for renewal and the required fees for certification at least three months prior to the expiration of the certificate.

R444-14-4. Method Approval.

(1) An applicant laboratory must request approval to analyze for an analyte or interdependent analyte group as part of its application for certification or renewal of certification. Approval to analyze for an analyte or interdependent analyte group upon application for certification or renewal of certification may be granted only after an on-site assessment. The applicant laboratory shall submit:

(a) documentation that it has the necessary equipment and trained technical employees to perform the tests;

(b) documentation that the laboratory has passed two proficiency testing audits for the analyte in question in a proficiency testing program;

(c) its standard operating procedure for the method used to analyze for the analyte in question;

(d) documentation of its initial demonstration of analytical capability; and

(e) documentation establishing the laboratory's method detection limit for the analyte.

(2) At a time other than at application for certification or renewal of certification, a certified laboratory may request approval to analyze for an additional analyte or interdependent analyte group by submitting a written request together with the documentation required in subsection (1).

(3) If the department is satisfied from its assessment that the applicant laboratory can produce valid results, it shall grant approval for the analyte or interdependent analyte group by a specific method.

(4) The department shall not grant approval to a laboratory that does not certify under this rule.

R444-14-5. Change in Name or Ownership.

(1) A certified laboratory that changes its name, business organizational status, or ownership must report the change in writing to the department within 30 days of the change.

(2) A certified laboratory that assumes a new business organizational status or ownership must maintain all the records required under this rule that the certified laboratory was required to maintain prior to the change in status or ownership.

R444-14-6. Access and Sample Testing.

(1) Applicants and certified laboratories shall allow department representatives access to the laboratory facility and records during laboratory operating hours to determine initial or continued compliance with this rule.

(2) The department may submit samples to applicant and certified laboratories in a manner that the applicant or certified laboratory is unaware of the expected values of the analytes in the samples.

R444-14-7. Quality Assurance.

(1) A certified laboratory must develop and implement a quality assurance program that is an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that its services meet its standards of quality with its stated level of confidence.

(2) The quality assurance program must meet the type and volume of testing activities the certified laboratory undertakes. The quality assurance program must include a quality assurance plan and the documentation of the quality assurance activities.

(3) As part of its quality assurance program, each certified laboratory must develop and adhere to a quality assurance plan. The quality assurance plan must be a written document and may incorporate other documents by reference. All technical employees must have easy access to the quality assurance plan. The certified laboratory must include and address the following essential items in the quality assurance plan:

(a) General quality control procedures;

(b) Frequency of proficiency testing;

(c) Proficiency testing audit handling;

(d) Reporting of proficiency testing results;

(e) Evaluation of staff competency;

(f) Staff training;

(g) Equipment operation and calibration;

(h) Analytical methods and SOPs;

(i) Physical facility factors that may affect quality;

(j) Sample acceptance policies and sample receipt policies;

(k) Sample tracking;

(l) Record keeping, quality assurance review of data, and reporting of results;

(m) Corrective action policy and procedures;

(n) Definitions of terms;

(o) Frequency and procedure of quality reviews and the content of reports to the director; and

(p) Frequency, procedure, and documentation of preventive maintenance.

(4) As part of the quality assurance program, the certified laboratory must document and retain records demonstrating compliance with its quality assurance program.

R444-14-8. Personnel Requirements and Responsibilities.

(1) A certified laboratory must:

(a) have a laboratory director who meets the qualification requirements of this section;

(b) have a laboratory quality assurance officer who meets the qualification requirements of this section, who may also serve as the laboratory director;

(c) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the quality of testing;

(d) have sufficient technical employees with the educational background and training necessary to perform all tests which the certified laboratory is approved to perform;

(e) adequately supervise its technical employees to assure quality test results;

(f) have a job a description for all key personnel and technical employees;

(g) maintain documentation of the qualifications of all key personnel;

(h) maintain a record of training for all key personnel and technical employees; and

(i) document and clearly describe the lines of responsibility of all key personnel and technical employees.

(2) The technical director is responsible for the administrative oversight and overall operation of the certified laboratory and must:

(a) define minimum qualifications, experience, and skills necessary for all technical employees;

(b) ensure and document through an annual competency check that each technical employee demonstrates initial and ongoing proficiency for the tests performed by the technical employee; and

(c) supervise the quality assurance officer and ensure the production and quality of all results reported by the certified laboratory.

(3) An individual may be the technical director of one certified laboratory.

(4) A technical director of a laboratory must have a bachelor's degree in the biological, chemical, or physical sciences, plus two years work experience in a certified laboratory or in a laboratory that the prospective technical director demonstrates to the department as one that substantially meets equivalent quality standards for a certified laboratory.

(5) The technical director is responsible for the day-to-day operation of the certified laboratory and:

(a) must supervise all technical employees of the certified laboratory;

(b) must assure that all samples are accepted in accordance with the requirement of this rule; and

(c) is responsible for the production and quality of all data reported by the certified laboratory.

(6) A quality assurance officer must:

(a) have documented training or experience in quality assurance procedures and be knowledgeable in the quality assurance requirements of this rule;

(b) have a knowledge of the approved methods the certified laboratory uses in order to allow him to verify that the certified laboratory is following the approved methods;

(c) not analyze samples as part of the regular analyses performed by the certified laboratory;

(d) have direct access to the highest level of management at which decisions are taken on laboratory policy and resources, and to the technical director;

(e) serve as the focal point for quality assurance and oversee and review quality control data;

(f) objectively evaluate data and objectively perform assessments;

(g) oversee all aspects of sample handling, testing, report collation and distribution with the purpose of the production of high quality results; and

(h) conduct or oversee and be responsible for an annual review of the entire technical operation of the certified laboratory.

(7) One individual may be the quality assurance officer of up to three certified laboratories.

R444-14-9. Physical Facilities.

(1) A certified laboratory must occupy physical facilities that have suitable space, energy sources, lighting, heating and ventilation to allow for proper performance of the testing.

(2) A certified laboratory must maintain the physical facilities to permit the production of quality results. The certified laboratory must assure that contamination is

unlikely, and must control variables that might adversely affect test results, such as: temperature; humidity; electrical power; vibration; electromagnetic fields; dust; direct sunlight; ventilation; and lighting.

(3) A certified laboratory must make available to technical employees an unencumbered work area to ensure that adequate working conditions are available for the tests.

(4) A certified laboratory must:

(a) control access to the laboratory;

(b) separate incompatible tests, analyses, procedures, materials, and the like; and

(c) have separate sample receipt, sample storage, chemical storage, waste storage, and data handling and storage areas.

R444-14-10. Equipment and Reference Materials.

(1) A certified laboratory must have on-site all equipment and apparatus, reagents, reference materials, and glassware necessary for the tests it performs. All equipment used to analyze samples must be in good working order.

(2) A certified laboratory must have SOPs on the use, operation, and maintenance of all equipment necessary for the analyses it performs.

(3) A certified laboratory must document and retain a record of the maintenance of its equipment. The documentation must include:

(a) name of item;

(b) manufacturer name;

(c) model and serial number;

(d) manufacturer's instructions;

(e) date received;

(f) date placed in service;

(g) current physical location;

(h) date and description of each maintenance activity; and

(i) date and description of each repair.

(4) In preparing or verifying all standard curves, a certified laboratory must use reference materials of documented high purity and traceability. The certified laboratory must document and retain a record of the origin, purity, traceability of all reference materials. The record must include the date the reference material was received, the date the reference material was opened, and the expiration date of the reference material.

(5) A certified laboratory must use water that is free from constituents that could potentially interfere with the sample preparation or testing. The certified laboratory must monitor and document and retain a record of the quality of the laboratory water used in testing.

(6) For water used in microbiological methods, a certified laboratory must analyze and document its laboratory water annually for bactericidal properties. For water used in microbiological testing, a certified laboratory must also analyze its laboratory water monthly and document the results for pH, chlorine residual, standard plate count, and conductivity, and the certified laboratory must also analyze the water annually and document the results for trace metals.

(7) A certified laboratory must use no less than analytical grade reagents. The certified laboratory must document and retain a record of the origin and purity of all reagents. The record must include the date of receipt of the reagent, the date the reagent was opened, and the expiration date of the reagent.

R444-14-11. Analytical Methods.

(1) A certified laboratory must have and maintain an in-house methods manual and SOPs. The methods manual and any associated reference works must be readily available to all technical employees.

(a) For each approved analyte or interdependent analyte group, the method used by the certified laboratory must be described in the methods manual. The method description or separate SOP must address the following:

(i) analyte name;

(ii) applicable matrix or matrices;

(iii) method detection limit;

(iv) scope and application;

(v) summary of the method;

(vi) any change to the approved method:

(vii) definitions;

(viii) interferences;

(ix) safety;

(x) equipment and supplies;

(xi) reagents and calibration standards;

(xii) sample collection, preservation, shipment and storage;

(xiii) quality control;

(xiv) calibration, validation and standardization procedures;

(xv) data analysis and calculations;

(xvi) method performance;

(xvii) pollution prevention;

(xviii) data review and acceptance criteria for QC measures;

(xix) waste management;

(xx) method identifier and references; and

(xxi) any tables, diagrams, flowcharts and validation data.

(2) The department may only approve a certified laboratory to analyze an analyte or interdependent analyte group by specific method. The department may only approve a certified laboratory for an analyte or interdependent analyte group using methods described in the July 1, 1992, 1993, 1994, 1995, 1996, 1997, 1998 and 1999 editions of 40 CFR Parts 141, 142, and 143 (Safe Drinking Water Act); 40 CFR Parts 136 and 503.8 (Clean Water Act); 40 CFR Parts 260 and 261 (Resource Conservation and Recovery Act).

(3) In analyzing a sample for compliance with the Safe Drinking Water Act, the Clean Water Act, or the Resource Conservation and Recovery Act, a certified laboratory must follow the method that it reports on its final report to have used.

(4) The department may approve a single method for analysis of an interdependent analyte group.

R444-14-12. Sample Management and Documentation.

(1) A certified laboratory must develop, document and implement a sample acceptance policy that clearly outlines the certified laboratory's sample acceptance requirements. The certified laboratory must make the sample acceptance policy readily available to all employees who accept samples and available to personnel who collect samples in the field. The sample acceptance policy must include that:

(a) the person submitting the sample must provide full documentation with the sample, which must include:

(i) sample identification;

(ii) the location, date, and time of collection;

(iii) collector's name; preservative added;

(iv) matrix; and

(v) any special remarks concerning the sample;

(b) each sample or group of samples must include trip blanks, field blanks, equipment blanks, duplicates or other field-submitted quality control measures as required by the method;

(c) each sample must be labeled with unique, durable, and indelible identification;

(d) each sample must show evidence of proper preservation and use of sample containers allowed by the test method; and

(e) each sample must be of adequate volume for the requested testing.

(2) A certified laboratory must develop, document and implement procedures that clearly outline the process to receive samples.

(3) A certified laboratory must check samples upon receipt for thermal and prior to analysis for chemical preservation as required by the method.

(a) The certified laboratory must document the results of preservation checks.

(b) For each sample that does not meet the preservation requirements of the test method, the certified laboratory must flag it upon receipt and continually throughout all phases of the analysis.

(4) A certified laboratory must properly store samples in containers and at temperatures specified by the method. The certified laboratory must document storage temperatures.

(5) A certified laboratory must develop and implement procedures to ensure and document that all samples and subsamples are analyzed within holding times.

(6) A certified laboratory must develop and implement a chronological log to document the receipt of each sample. The certified laboratory must record the following in the log:

(a) date of receipt at the laboratory;

(b) date the sample was collected;

(c) unique laboratory identification code required in R444-14-12(7)(a);

(d) field identification code if supplied by the submitter;

(e) requested analysis, including method number, if applicable; and

(f) comments documenting sample rejection.

(7) A certified laboratory must uniquely identify all samples and all subsamples.

(a) The certified laboratory must assign and document a unique identification code to each sample container received in the laboratory and attach a durable label with the unique identification code to the sample container.

(b) The certified laboratory must establish and document a link from subsamples back to the original sample.

(c) The certified laboratory shall treat all samples from public water supplies as routine compliance samples, except those samples for which the request clearly indicates that the samples are submitted as repeat or noncompliance samples.

(8) Each certified laboratory must have a record keeping system that allows historical reconstruction of all laboratory activities that produce analytical data.

(a) The certified laboratory must document, either in hard copy or machine readable format, all original raw data for each sample and subsample for the testing performed on each sample and subsample.

(b) The certified laboratory must associate the raw data from the test with a laboratory sample identification number, the date of analysis, instrument used, method used, actual calculations, and the technical employee's initials or signature.

(c) The certified laboratory must document which procedures, methods, laboratory forms, policies, equipment, personnel were used to produce the result for each test.

(9) A certified laboratory must retain all correspondence and notes from conversations concerning the final disposition of samples that the certified laboratory has rejected and must document any decision to proceed with the analysis of compromised samples which were improperly sampled, or were received with insufficient documentation, were improperly preserved, were received in the wrong containers, or were received beyond the holding time.

(10) The certified laboratory must produce a final report of its analysis.

(a) The final report must document the method used to produce each result. If the certified laboratory deviated from the test method used in producing the result, the method description on the final report must indicate that the method was modified. The certified laboratory must describe on the final report any abnormal condition of the sample, deviation from holding time, or preservation requirements that in the judgement of the certified laboratory might affect the result. The certified laboratory must produce the final report in such a way that the information required by this subsection is unambiguous, is inseparable from the final result, and that clearly defines the nature and substance of the variation.

(b) The certified laboratory must make a final report in a single identifiable document. It shall accurately, clearly, unambiguously, and objectively give the results in a manner that is understandable to the client. The basic information in the final report must include the following:

(i) report title with the name, address and phone number of the certified laboratory;

(ii) the name of client or project, and the client identification number;

(iii) description and laboratory identification code of the sample;

(iv) the dates of sample collection, sample receipt, sample preparation, and sample analysis;

(v) the time of either sample preparation or analysis or both if the required holding time for either activity is 48 hours or less;

(vi) a method identifier for each method, including methods for preparation steps, used to produce the test result;

(vii) the MDL or minimum reporting limit for the test result;

(viii) the test result;

(ix) a description of any quality control failures and deviations from the accepted method or methods;

(x) the signature and title of the individuals who accept responsibility for the content of the report;

(xi) date of issue; and

(xii) a clear identification of any result generated by a laboratory other than the laboratory producing the report, with the name and address of the subcontracted laboratory.

(c) The certified laboratory must support by supplementary documentation any correction, addition or deletion from an original final report after it has been issued. Any correction, addition or deletion must clearly identify its purpose, and must meet all reporting requirements of this rule.

(d) If authorized by the public water system, the certified laboratory must also report the results of routine compliance drinking water samples from the public water system to the Department of Environmental Quality, Division of Drinking Water. Reports to the Department of Environmental Quality, Division of Drinking Water may be filed electronically or by other means acceptable to Department of Environmental Quality, Division of Drinking Water.

(11) If a certified laboratory offers that it can document chain of custody in its testing to meet legal and evidentiary standards, the certified laboratory must establish procedures to establish and document chain of custody sufficient to meet legal and evidentiary standards.

(12) A certified laboratory must retain for five years all documentation required by this rule.

(a) If the certified laboratory retains in a machine readable format any documentation required by this rule, the certified laboratory must maintain it in a protected form that either prohibits or clearly indicates any deletion or alteration to the documentation.

(b) All documentation required by this rule must be available to the department.

R444-14-13. Proficiency Testing.

For a certified laboratory to become approved and to maintain approval for an analyte or an interdependent analyte group by a specific method, the certified laboratory must, at its own expense, meet the proficiency testing requirements of this rule.

(1) The certified laboratory must enroll and participate in a proficiency testing program for each analyte or interdependent analyte group. For each analyte or interdependent analyte group for which proficiency testing is not available, the certified laboratory must establish, maintain, and document the accuracy and reliability of its procedures through a system of internal quality management.

(a) The certified laboratory must participate in more than one proficiency testing program if necessary to be evaluated to obtain or maintain approval to analyze an analyte or interdependent analyte group.

(b) The certified laboratory must, prior to obtaining approval, notify the department of the authorized proficiency testing program or programs in which it has enrolled for each analyte or interdependent analyte group.

(2) The certified laboratory must follow the proficiency testing provider's instructions for preparing the proficiency testing sample and must analyze the proficiency testing sample as if it were a client sample.

(a) The certified laboratory must notify the department before the certified laboratory changes enrollment in an authorized proficiency testing program.

(b) The certified laboratory must direct the proficiency testing provider to send, either in hard copy or electronically, a copy of each evaluation of the certified laboratory's proficiency testing audit results to the department. The certified laboratory must allow the proficiency testing provider to release all information necessary for the department to assess the certified laboratory's compliance with this rule.

(c) The following are strictly prohibited:

(i) performing multiple analyses (replicates, duplicates) which are not normally performed in the course of analysis of routine samples;

(ii) averaging the results of multiple analyses for reporting when not specifically required by the method; or

(iii) permitting anyone other than bona fide laboratory employees who perform the analyses on a day-to-day basis for the certified laboratory to participate in the generation of data or reporting of results.

(3) In each calendar year, the certified laboratory must complete at least two separate proficiency testing audits for each analyte or interdependent analyte group.

(4) The certified laboratory may not:

(a) discuss the results of a proficiency testing audit with any other laboratory until after the deadline for receipt of results by the proficiency testing provider;

(b) if the certified laboratory has multiple testing sites or separate locations, discuss the results of a proficiency testing audit across sites or locations until after the deadline for receipt of results by the proficiency testing provider;

(c) send proficiency testing samples or portions of samples to another laboratory to be tested; or

(d) knowingly receive a proficiency testing sample from another laboratory for analysis and fail to notify the department of the receipt of the other laboratory's sample within five business days of discovery.

(5) The certified laboratory must maintain a copy of all proficiency testing records, including analytical worksheets. The proficiency testing records must include a copy of the authorized proficiency testing provider report forms used by the laboratory to record proficiency testing results,

(a) The director of the certified laboratory must sign and retain an attestation statement stating that the certified laboratory followed the proficiency testing provider's instructions for preparing the proficiency testing sample and analyzed the proficiency testing sample as if it were a client sample.

(b) The certified laboratory must analyze and report the results of the proficiency testing test by the deadline set by the proficiency testing provider.

(6) Upon receipt of the evaluation of the results from the proficiency testing provider, the department shall assign a grade for each analyte where:

(a) "Acceptable" equals 100;

(b) "Not acceptable" equals zero; and

(c) "Nonparticipation" equals zero.

(7) The certified laboratory must receive a grade of 100 for any single analyte to pass a proficiency testing audit for that analyte. The certified laboratory must receive an average grade of 80 for any interdependent analyte group to pass a proficiency testing audit for the interdependent analyte group.

(a) If the proficiency testing evaluation is to obtain or maintain approval for an interdependent analyte group by a single method, the grade for the interdependent analyte group is the average of the grades for the individual analytes in the evaluation of the results from the proficiency testing provider.

(b) If the proficiency testing evaluation is of multiple concentrations of a single analyte, the department shall average the grades for individual concentrations and assign the average as the grade for the analyte.

(8) If the certified laboratory fails a proficiency testing audit, it must submit a corrective action plan to the department.

R444-14-14. Quality System.

(1) A certified laboratory must adhere to the requirements found in Chapter 5, Quality Systems, of the National Environmental Laboratory Accreditation Conference Standards approved July 1999, which are incorporated by reference.

R444-14-15. Corrective Action Procedure.

(1) A certified laboratory must develop written SOPs that govern its response to quality control results that are outside acceptance ranges that the certified laboratory has established to meet the requirements of the method or this rule. The SOPs must address the following:

(a) identification of anticipated problems and the anticipated or recommended corrective action to correct or eliminate the problem and future occurrences of the problem; and

(b) requirements for written records that document both anticipated and unanticipated problems, the corrective measures taken, and the final outcome of the corrective action.

(2) A certified laboratory must have written policy and procedures for the resolution of complaints it receives about the laboratory's activities. The certified laboratory must document and maintain records of complaints and of the actions taken by the laboratory in response to each complaint.

(3) A certified laboratory must document a response to each deficiency noted on the department written report of the department's findings from an on-site assessment.

(4) A certified laboratory must have written policy and procedures to identify the cause and resolve the cause for a failed proficiency testing audit. The certified laboratory must document and maintain records of its actions taken to resolve the cause for the failure.

R444-14-16. Denial, Suspension and Revocation.

(1) The department may suspend the certificate of a certified laboratory for an approved analyte or interdependent analyte group if the certified laboratory fails two of three of its most recent proficiency testing audits required by section R444-14-13. The department may remove the suspension of a certified laboratory for an analyte or an interdependent analyte group if the certified laboratory passes the next two proficiency testing audits required by section R444-14-13.

(2) The department shall revoke approval for a an analyte or an interdependent analyte group if the approval for the analyte or the interdependent analyte group is under department suspension and if the certified laboratory fails a proficiency testing audit required by section R444-14-13.

(3) If a certified laboratory fails to submit a corrective action plan to the department within thirty days of the department's sending a notice of failure of a proficiency testing audit required by section R444-14-13, the department shall revoke the approval for the analyte or interdependent analyte group.

(4) If the department has revoked a certified laboratory's approval for an analyte or interdependent analyte group because of failure of a proficiency testing audit in three of the last four proficiency testing audits required under section R444-14-13, the certified laboratory may seek approval, but not prior to 6 months from the revocation of approval. The certified laboratory may seek this approval by:

(a) requesting approval in writing for the analyte or interdependent analyte group; and

(b) passing two proficiency testing audits under section R444-14-13.

(5) The department may revoke approval for an analyte or interdependent analyte group if a certified laboratory does not adhere to the approved method or to the quality system requirements of this rule.

(6) The department may deny certification if the applicant laboratory:

(a) fails to meet the personnel qualifications for key personnel, including the education, training and experience requirements as required by the department;

(b) refuses the certification officer entry to the laboratory for any on-site assessment;

(c) refuses the certification officer access to the laboratory records for any assessment; or

(d) fails to correct deficiencies identified in a prior on-site assessment.

(7) If the department denies certification because the applicant laboratory submitted an unacceptable corrective action plan, the applicant laboratory may submit only one additional corrective action plan to remedy the deficiencies. If the department determines that the corrective action plan is insufficient to correct the deficiencies, the applicant laboratory must wait six months before again applying for certification.

(8) The department may suspend a certified laboratory if the certified laboratory fails to notify the department within 30 calendar days of changes in key personnel or laboratory location.

(9) The department may revoke a certified laboratory's certification for a minimum of one year if it:

(a) submits a proficiency testing sample to another laboratory for analysis;

(b) submits proficiency testing sample results generated by another laboratory as its own;

(c) receives a proficiency testing sample from another applicant or certified laboratory for analysis and fails to notify the department of the receipt of other certified laboratory's sample within five business days of discovery;

(d) falsifies data on any report or is involved in any other deceptive practice;

(e) misrepresents any material fact pertinent to receiving certification; or

(f) fails to correct deficiencies from an on-site assessment by the date agreed to in the corrective action plan.

(10) The department may revoke a certified laboratory's certification if it:

(a) refuses the certification officer entry to the certified laboratory for an on-site assessment;

(b) permits persons other than its employees to perform or report results of analyses governed by this rule;

(c) does not meet the personnel requirements and responsibilities under R444-14-8; or

(11) The department shall revoke a certified laboratory's certification if it fails to pay its annual certification or approval fee within 90 calendar days of invoice. The department may revoke a certified laboratory's certification if it fails to pay any approval fee within 90 calendar days of invoice. A laboratory whose certification has been revoked for failure to pay certification or approval fees may not reapply for certification until it pays past due fees.

(12) The Department may suspend the laboratory's certification if the department finds the public interest, safety, or welfare requires emergency action.

R444-14-17. Recognition of NELAP Accreditation.

The department may certify a laboratory that is NELAP-accredited. A laboratory seeking certification because of its NELAP accreditation must provide evidence of its accreditation and apply for certification on that basis. A laboratory certified on the basis of NELAP accreditation must obtain approval from the department for each analyte or interdependent analyte group and meet the approval requirements of this rule.

R444-14-18. Penalties.

A laboratory violates this rule and is subject to the penalties provided in Title 26, Chapter 23, including administrative and civil penalties of up to $5,000.00 for each offense, criminal sanctions of a class B misdemeanor on the first offense and a class A misdemeanor on the second offense, and criminal penalties of up to $5,000.00 for each offense if it:

(1) without being certified under this rule, holds itself out as one capable of testing samples for compliance with Federal Safe Drinking Water Act, Federal Clean Water Act, Federal Resource Conservation and Recovery Act; or

(2) without being approved to analyze for the analyte or interdependent analyte group, analyzes samples for the analyte or interdependent analyte group for compliance with rules established by the Utah Department of Environmental Quality that require that the analysis be conducted by a certified laboratory.

Key:
laboratories

Date of Last Substantive Amendment:
March 1, 2000

Notice of Continuation:
June 12, 1997

Authorizing Law:
This rule is authorized by, and implements or interprets, the following:
26-1-30(2)(m)